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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/330,909	06/11/1999	JON A. WOLFF	MIRUS.011.01	1001

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

29

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application N .	Applicant(s)	
	09/330,909	WOLFF ET AL.	
	Examiner	Art Unit	
	Joseph T. Voitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,12-14,18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-6,12-14,18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application claims benefit to provisional applications 60/100,168, filed September 14, 1998.

Applicants amendment filed August 1, 2003, paper number 28, has been received and entered. The specification has been amended. Claims 16 and 17 have been canceled. Claims 1 and 18 have been amended. Claims 1, 2, 4-6, 12-14, 18, 20-22 are pending and currently under examination.

Response to Amendment

The declaration of Hans Herwijer filed on August 1, 2003, attachment to paper number 28, under 37 CFR 1.131 has been considered and is effective to overcome the 35 USC 102(e) rejection made over the Mann *et al.* reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
Claims 16 and 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention is withdrawn. Cancellation of the claims has rendered the basis of the rejection moot.

Claims 5 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in practicing the method of claim 1 the hydrostatic pressure increases the permeability of the lumen of the vessel allowing the nucleic acid to be delivered to cardiac muscle cells outside. It is unclear how claims 5 and 13 further limit the inherent property of increasing the permeability of the vessel provided for in the practice of the method. If claims 5 and 13 represent additional steps or a particular modification of claim 1, more clearly detailing the relationship of increasing the permeability beyond that obtained by the hydrostatic pressure.

Claim Objections

Claims 1, 2, 4-6, 12-14, 18, 20-22 are objected to because of the following informalities: the specific steps set forth in claim 1 are not clearly set forth with respect to the relationship of each of the steps. Specifically, in claims 1 and 18 step (c) should more clearly indicate that the injecting is done near or in the heart. Amendment the claim to read 'into the blood vessel near or in the heart, *in vivo*, and [; (c)] injecting a solution' would obviate the basis of the objection. Further, step (d) only describes what is accomplished by the act of injecting and increasing the hydrostatic pressure. Amendment to the claim to read 'hydrostatic pressure in the lumen thereby [; and , d)] delivering the nucleic acids to the heart muscle' would obviate the basis of the

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objection. Additionally for claim 18, the claim should be amended to reflect the change in step number. Dependent claims 2, 4-6, 12-14, 20-22 are included in the basis of the objection because the fail to address the issues set forth above.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1, 2, 4-6, 12-14, 18, 20-22 rejected under the judicially created doctrine of double patenting over claims 1-4 of U. S. Patent No. 6,627,616 B2 (issued September 30, 2003)

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: In each case the methods are generally drawn to the delivery of a polynucleotide to an extravascular cell, reciting method steps for delivery of the nucleic acids from inside a vessel into extravascular cells. In particular the use of hydrostatic pressure is specifically recited in claim 2 of '616. The use and practice of the method set forth in '616 is broad and not limited to practice in any particular tissue. Further, the specification specifically contemplates practicing the method in a variety of tissues, including cardiac tissue. The practice of the method in cardiac tissue as set forth in the instant application would be an obvious and specific tissue contemplated by '616.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(f) he did not himself invent the subject matter sought to be patented.

Claims 1, 2, 4-6, 12-14, 18, 20-22 rejected under 35 U.S.C. 102(e) as being clearly anticipated by Mann *et al.* (US patent # 5,922,687) is withdrawn.

As indicated above, the declaration of Hans Herwijer filed under 37 CFR 1.131 is sufficient to antedate the anticipation of the Mann *et al.* reference.

Claims 1, 2, 4-6, 12-14, 18, 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Monahan *et al.* (US Patent 6,627,616).

The applied reference has a common inventor with the instant application, however the inventive entity for each is different. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In the instant case the specification of '616 teaches methods for the *in vivo* delivery of a polynucleotide via a vessel (set forth in claim 1) and specifically contemplates the use of hydrostatic pressure to affect delivery outside the vessel (set forth in claim 2). Upon review of the disclosure of '616, the method can be used to transfect an entire animal (set forth in claim 4) or used more locally for particular tissues including the heart (column 3, line 1). Monahan *et al.* provide specific teaching anticipating each of the method steps set forth in the pending claims.

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Claims 1, 2, 4-6, 12-14, 18, 20-22 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Specifically, as set forth above, the specification and the claims of Monahan *et al.* make obvious the instantly claimed invention. In particular, it is unclear how the claims of '616 for use in any tissue which are broader than instantly claimed (for use in cardiac tissue) would not have at least the same inventors as '616.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


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